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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEPHEN D. CASSIVI

Appeal 2015-001053
Application 13/062,908
Technology Center 3700

Before JENNIFER D. BAHR, JOHN C. KERINS, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

BAHR, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Stephen D. Cassivi (Appellant) appeals under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 1, 6–10, 14–23, 25, 27, 28, and 30–34. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

THE CLAIMED SUBJECT MATTER

Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A kit for buttressing tissue at an internal body location, the kit comprising:

one or more sheets of buttress material in a package, wherein the buttress material is configured for delivery and attachment to tissue using a stapler;

radioactive material in the package, wherein the radioactive material is configured for attachment to the one or more sheets of buttress material; and

carrier material in the package, wherein the carrier material is separate from the buttress material, and wherein the radioactive material is provided integrally with the carrier material.

REJECTIONS

- I. Claims 1, 7, 9, 10, and 15 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger (US 2009/0001122 A1, pub. Jan. 1, 2009) and Oray (US 2006/0173470 A1, pub. Aug. 3, 2006).
- II. Claim 6 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Oray, and Ostapoff (US 2010/0059570 A1, pub. Mar. 11, 2010).
- III. Claims 8 and 14 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Oray, and Chan (US 6,793,798 B2, iss. Sept. 21, 2004).
- IV. Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Oray, and Wazer (US 8,267,849 B2, iss. Sept. 18, 2012).

- V. Claims 16–23, 27, 28, 33, and 34 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger and Ostapoff.
- VI. Claim 25 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Ostapoff, and Zubik (US 7,377,928 B2, iss. May 27, 2008).
- VII. Claim 30 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Ostapoff, and Soltz (US 2007/0179528 A1, pub. Aug. 2, 2007).
- VIII. Claims 30 and 31 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Ostapoff, and Tilton (US 5,919,184, iss. July 6, 1999).
- IX. Claim 32 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Ostapoff, and Oray.¹

DISCUSSION

Claims 1, 6–10, 14, and 15

Claim 1 recites a *kit* comprising, *in a package*, one or more sheets of buttress material, carrier material separate from the buttress material, and radioactive material provided integrally with the carrier material. Appeal Br., Claims App. The Examiner finds that Prommersberger discloses one or more sheets of buttress material (non-porous layer 360) and carrier material

¹ The Examiner does not expressly restate Rejections VI–IX in the Answer, but does state that every ground of rejection set forth in the Final Rejection, from which the present appeal is taken, “is being maintained . . . except for the grounds of rejection (if any) listed under the subheading ‘WITHDRAWN REJECTIONS.’” Ans. 2. The Answer does not include a “subheading ‘WITHDRAWN REJECTIONS.’”

(porous layer 370) separate from the buttress material. Final Act. 3 (citing Prommersberger ¶¶ 21, 41–42; Figs. 3A, 3B); *see also* Ans. 2. With respect to the limitation that the carrier material is separate from the buttress material, the Examiner notes that “Prommersberger teaches the non-porous layer and the porous layer may be connected to one another to form the multi-layer buttress material and the porous layer may be formed separate and apart from the non-porous layer.” Final Act. 3 (citing Prommersberger ¶ 41–42). According to the Examiner, “under a broadest reasonable interpretation of ‘separate,’ different or distinct layers of material, such as the porous and non-porous layers [of Prommersberger’s buttress 350] would satisfy” the limitation in claims 1 and 10 of carrier material that is separate from the buttress material. Ans. 4–5 (citing a dictionary definition of “separate” to establish that “[w]hile separate can mean ‘not joined or touching physically,’ it can also mean ‘different; distinct’”).

Relying on the description of a kit provided in sealed package 250 set forth on page 16 of the Specification and the illustration of such a kit in Figure 3 of the present application, Appellant submits that “a skilled artisan would understand the feature ‘wherein the carrier material is separate from the buttress material’ to mean that the carrier materials and the buttress materials are provided as separate components – not merely that, as the Examiner suggests, the materials are ‘different or distinct layers of material.’” Reply Br. 2–4. In particular, Appellant points out that “the present application explicitly contrasts components ‘provided integrally with each other’ with ‘separate components.’” *Id.* at 3 (citing Spec. 16:16–18).

We agree with Appellant. Appellant’s Specification discloses that a kit according to the invention may include components such as staples,

buttress material, radioactive material, carrier material, and a medically useful agent provided in a sealed package and that “two or more of these components may be provided integrally with each other although they are depicted as separate components within the kit.” Spec. 16:8–18. Thus, within the context of the kit, Appellant’s Specification does distinguish, or contrast, “separate components within the kit” and components “provided integrally with each other.” Moreover, claim 1 similarly incorporates these disparate modifiers for the relationship between the carrier material and the buttress material (i.e., “wherein the carrier material is separate from the buttress material”) and the relationship between the radioactive material and the carrier material (i.e., “wherein the radioactive material is provided integrally with the carrier material”). Accordingly, when viewing the language of claim 1 within the context of the claim as a whole and in light of the Specification, a person having ordinary skill in the art would not consider the porous and non-porous layers of Prommersberger’s buttress 350 to be “separate” from one another as recited in claim 1.

We appreciate that Prommersberger discloses that “[t]he porous layer may be formed separate and apart from the non-porous layer” and that the multilayer buttress material may be formed by connecting the non-porous layer to the porous layer. Prommersberger ¶41–42. Thus, Prommersberger contemplates that at some point in time after the porous and non-porous layers have been formed separate and apart from one another and before they are connected to form the multilayer buttress element, the porous layer and the non-porous layer exist as physically separate, unattached elements. However, the Examiner does not point to, nor do we discern, any disclosure by Prommersberger of providing the physically separate, unattached porous

layer and non-porous layer *in a package* as part of a *kit*, as called for in claim 1. Relying on teachings in paragraph 33 of Oray, the Examiner determines that it would have been obvious to provide the buttress and bioactive agent of Prommersberger in a package. Final Act. 4. However, the Examiner does not articulate any reason why a person having ordinary skill in the art would have been prompted to provide the physically separate, unattached porous layer and non-porous layer in such a package. The Examiner does not rely on any of Ostapoff, Chan, or Wazer for any teaching that might overcome this deficiency in the combination of Prommersberger and Oray. *See* Final Act. 5–7.

For the above reasons, the Examiner fails to establish by a preponderance of the evidence that the combination of Prommersberger with Oray alone or in further combination with Ostapoff, Chan, or Wazer renders obvious a kit comprising one or more sheets of buttress material and carrier material separate from the buttress material in a package, as called for in claim 1. Accordingly, we do not sustain the rejections of claims 1, 6–10, 14, and 15 under 35 U.S.C. § 103(a).

Claims 16–23, 25, 27, 28, and 30–32

In contesting the rejections of these claims (*see* Final Act. 7–10, 12–16), Appellant argues that “[n]othing in Prommersberger paragraphs 41 and 42 teaches or suggests that ‘a carrier element that is separate from a buttress element’ is provided as part of a surgical fastening device, as required by claim 16.” Appeal Br. 12.

As discussed above, Appellant’s Specification describes providing several components, such as carrier and buttress materials, separately (i.e., in a non-integral manner) from one another in a sealed package to form a kit,

which can then be used to form a surgical fastening device. Spec. 16:5–22; Fig. 3. However, in describing the surgical fastening device, Appellant’s Specification and drawings disclose the carrier material being a portion of or attached to the buttress material. *See, e.g.*, Spec. 8:24–25; 9:15–16; 12:10–13.² Thus, the Examiner’s interpretation of a carrier element “separate” from the buttress element in claim 16 as encompassing “different or distinct layers of material, such as the porous and non-porous layers” of Prommersberger’s buttress 350 (Ans. 4–5) is reasonable in light of the description of the surgical fastening device in Appellant’s Specification.

Moreover, even applying Appellant’s urged construction of “separate” as excluding layers that are connected to one another (Reply Br. 4) to claim 16, Prommersberger’s disclosure of a porous layer and a non-porous layer formed separate and apart from one another, prior to being connected to one another to form a multilayer buttress, satisfies the limitation of “a carrier element that is separate from the buttress element.” *See* Prommersberger ¶¶ 41–42; Final Act. 8.

For the above reasons, Appellant’s argument does not apprise us of error in the Examiner’s rejections of claims 16–23, 25, 27, 28, and 30–32 under 35 U.S.C. § 103(a). Accordingly, we sustain the rejections of these claims.

Claims 33 and 34

In contesting the rejection of claims 33 and 34, Appellant groups claims 33 and 34 together. Appeal Br. 13–16. We select claim 33 as

² Notably, Appellant cites to each of these portions of the Specification as providing support for the limitation “radioactive material attached to a carrier element that is separate from the buttress element” in claim 16. Appeal Br. 5.

representative of this group, and claim 34 stands or falls with claim 33. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Claim 33 is directed to “[a] method [of] buttressing a staple line and providing radiation therapy” comprising, in pertinent part, “attaching buttress material to selected tissue using staples” and “attaching radioactive material to the buttress material by attaching carrier material to the buttress material using the staples, wherein the radioactive material is integral with the carrier material.” Appeal Br., Claims App. The Examiner finds that Prommersberger discloses a method including “‘attaching buttress material to selected tissue using staples’ and ‘attaching carrier material to the buttress material using the staples.’” Final Act. 11. The Examiner also finds that Prommersberger discloses a bioactive agent, which “may be any agent which provides a therapeutic or prophylactic effect,” combined with either the buttress material or the carrier material (i.e., the porous layer or the non-porous layer). *Id.* (citing Prommersberger ¶ 51). However, the Examiner acknowledges that “Prommersberger does not teach the bioactive agent is a radioactive material or provided radiation therapy.” *Id.*

The Examiner finds that Ostapoff teaches combining radiotherapeutic agents, such as radioisotopes like iodine 125 and palladium 103, with buttress material, such as a film, for use in brachytherapy, for example. *Id.* at 11–12 (citing Ostapoff ¶¶ 52, 59, 60). In view of Ostapoff’s teachings, the Examiner determines it would have been obvious “to modify the bioactive agent combined with the porous layer of Prommersberger to be radioactive as taught by Ostapoff in order to provide a therapeutic or prophylactic effect and use the film for brachytherapy.” *Id.* at 12. Appellant

does not contest the Examiner's determination that such a modification would have been obvious. *See* Appeal Br. 13–15.

Appellant asserts “that the Examiner provided no explanation as to why ‘attaching radioactive material to the buttress material by attaching carrier material to the buttress material using the staples’ as claimed would have been obvious.” *Id.* at 13. According to Appellant, “[a]ttaching carrier material to the buttress material using staples’ – which the Examiner did address – is not equivalent to ‘attaching radioactive material to the buttress material by attaching carrier material to the buttress material using the staples.’” *Id.* at 14.

In response, the Examiner explains that the porous and non-porous layers of Prommersberger's multilayer buttress “are equated to the claimed buttress material and carrier material” and that Prommersberger's teaching of “firing a stapling apparatus to force at least one staple to pass through the openings on the staple cartridge, at least one multilayer buttress, . . . the tissue, and the openings on the staple anvil to seal the tissue” constitutes a teaching of “attaching buttress material to selected tissue using staples.” Ans. 5 (citing Prommersberger ¶ 19). The Examiner adds that “even though the carrier material and buttress material are already physically attached as part of the multi-layer buttress, using staples to attach the multi-layer buttress to tissue, would be a second means by which the carrier material is attached to the buttress material using the staples.” *Id.*

We agree with the Examiner. Notably, claim 33 does not exclude other means of attachment of the carrier material and/or the radioactive material to the buttress material in addition to the staples that attach the buttress material, carrier material, and radioactive material to one another

and to the selected tissue. In fact, the portions of Appellant's Specification cited in the Appeal Brief as providing support for the limitation "attaching radioactive material to the buttress material by attaching carrier material to the buttress material using the staples" describe a method in which carrier elements are attached to the buttress materials prior to stapling. *See* Appeal Br. 5 (citing Spec. 10:29–11:2; 14:15–27); Spec. 10:29–32 (describing, "[i]n some embodiments, the radioactive material may be attached to the buttress element, either directly or attached via another material (e.g., a carrier element, etc.) before the buttress element is used as a surgical fastener (e.g., before the buttress element is stapled"); Spec. 14:15–17 (describing, in Figure 1, "a first carrier element 122 is attached to the second layer of buttress material 120 and a second carrier element 124 is attached to the first layer of buttress material 118"). When the stapling apparatus is fired to force staples to pass through at least one multilayer buttress and the tissue, as disclosed in paragraph 19 of Prommersberger, the steps of attaching buttress material (e.g., the non-porous layer) to selected tissue using staples and attaching radioactive material (as the bioactive agent combined with the porous layer, in view of Ostapoff) to the buttress material by attaching carrier material (e.g., the porous layer) to the buttress material using the staples, as called for in claim 33, are performed.

For the above reasons, Appellant fails to apprise us of error in the rejection of claims 33 and 34 under 35 U.S.C. § 103(a). Accordingly, we sustain the rejection of claims 33 and 34.

DECISION

The Examiner's decision rejecting claims 1, 7, 9, 10, and 15 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger and Oray is REVERSED.

The Examiner's decision rejecting claim 6 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Oray, and Ostapoff is REVERSED.

The Examiner's decision rejecting claims 8 and 14 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Oray, and Chan is REVERSED.

The Examiner's decision rejecting claim 8 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Oray, and Wazer is REVERSED.

The Examiner's decision rejecting claims 16–23, 27, 28, 33, and 34 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger and Ostapoff is AFFIRMED.

The Examiner's decision rejecting claim 25 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Ostapoff, and Zubik is AFFIRMED.

The Examiner's decision rejecting claim 30 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Ostapoff, and Soltz is AFFIRMED.

The Examiner's decision rejecting claims 30 and 31 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Ostapoff, and Tilton is AFFIRMED.

The Examiner's decision rejecting claim 32 under 35 U.S.C. § 103(a) as unpatentable over Prommersberger, Ostapoff, and Oray is AFFIRMED.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART